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Addison et al.

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(54) **SILICONE GEL-COATED WOUND DRESSING**

(75) Inventors: **Deborah Addison**, Nr Clapham (GB); **Sally Stephens**, Skipton (GB); **Rachel Hadley**, Ulverston (GB)

(73) Assignee: **KCI USA, Inc.**, San Antonio, TX (US)

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CPC A61L 15/58; C09J 7/045
USPC 427/2.31, 208, 532; 602/54
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,696,854 A 9/1987 Ethier
4,991,574 A 2/1991 Pocknell
(Continued)

FOREIGN PATENT DOCUMENTS

EP 1452156 A1 9/2004
JP 2116370 A 10/1988
(Continued)

OTHER PUBLICATIONS

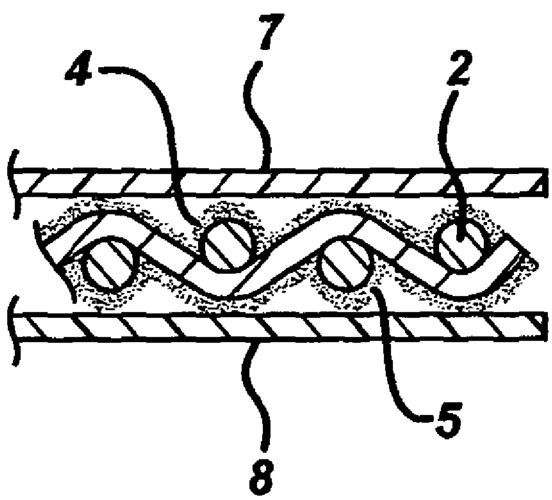
PCT International Search Report and Written Opinion dated Dec. 16, 2011.

Primary Examiner — Cachet Sellman

(57) **ABSTRACT**

A wound dressing product comprising: a substrate layer having an upper surface and a lower surface; a tacky silicone coating composition present on said upper surface and on said lower surface; and upper and lower release sheets covering said substrate and said tacky silicone coating composition on said upper and lower surfaces, respectively, and adhered to said surfaces by said tacky silicone coating composition, wherein said upper surface is less tacky than said lower surface whereby said upper release sheet can be removed from said upper surface more readily than said lower release sheet can be removed from said lower surface. The same silicone composition is used to form both the upper and the lower surface. Also provided are methods for making such dressings.

16 Claims, 4 Drawing Sheets



(51) **Int. Cl.**

A61L 15/26	(2006.01)
A61F 13/02	(2006.01)
B65B 55/02	(2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,891,076	A	4/1999	Fabo	
6,472,581	B1 *	10/2002	Muramatsu	A61L 15/26 602/41
6,846,508	B1 *	1/2005	Colas	A61L 15/58 427/2.1
7,119,247	B2 *	10/2006	Worthley	A61F 13/0276 602/42
2004/0219355	A1 *	11/2004	Clemmens	C09J 7/043 428/343
2011/0160686	A1 *	6/2011	Ueda	A61F 13/0203 604/365

FOREIGN PATENT DOCUMENTS

JP	10095072	A	9/1996
JP	2006181816	A	7/2006
WO	2007113597	A2	10/2007

* cited by examiner

FIG. 1

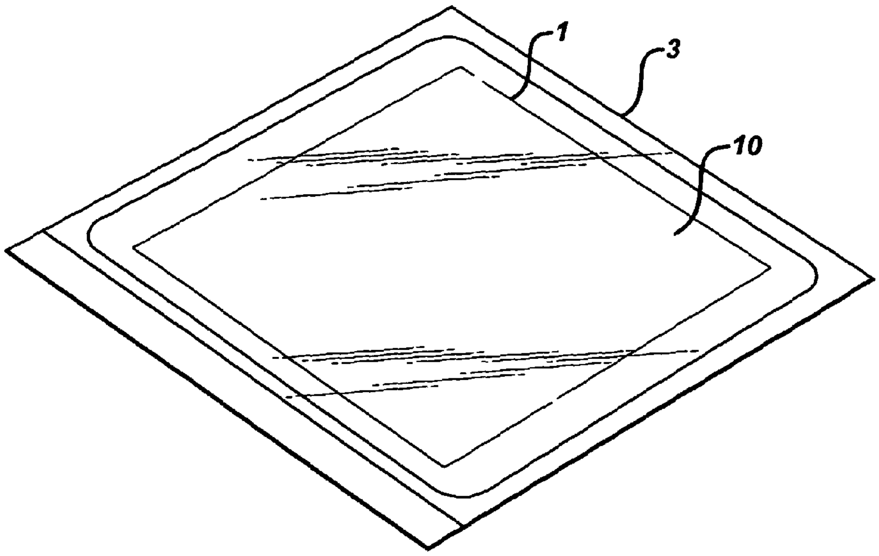


FIG. 2

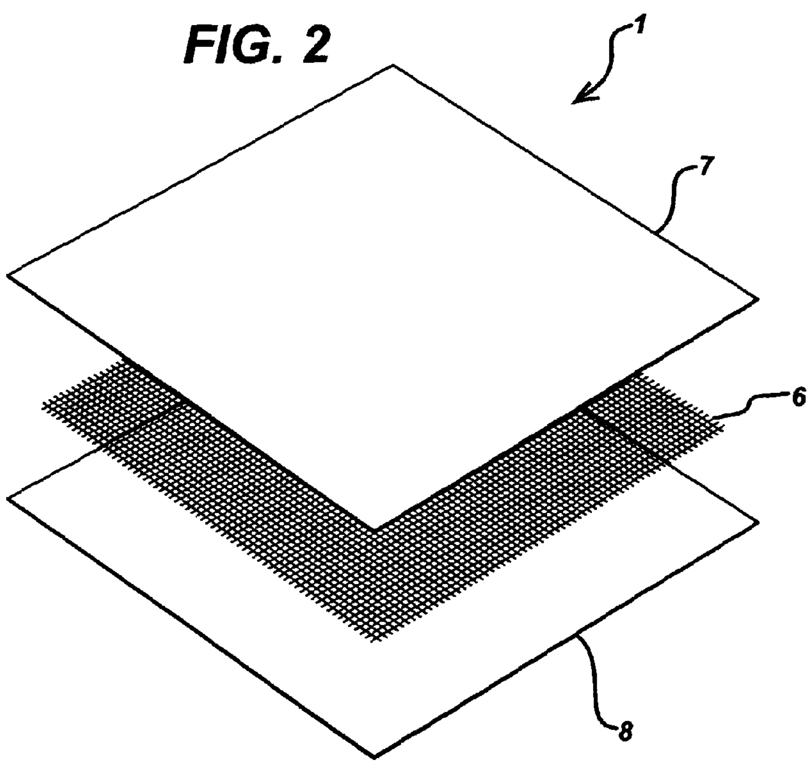


FIG. 3

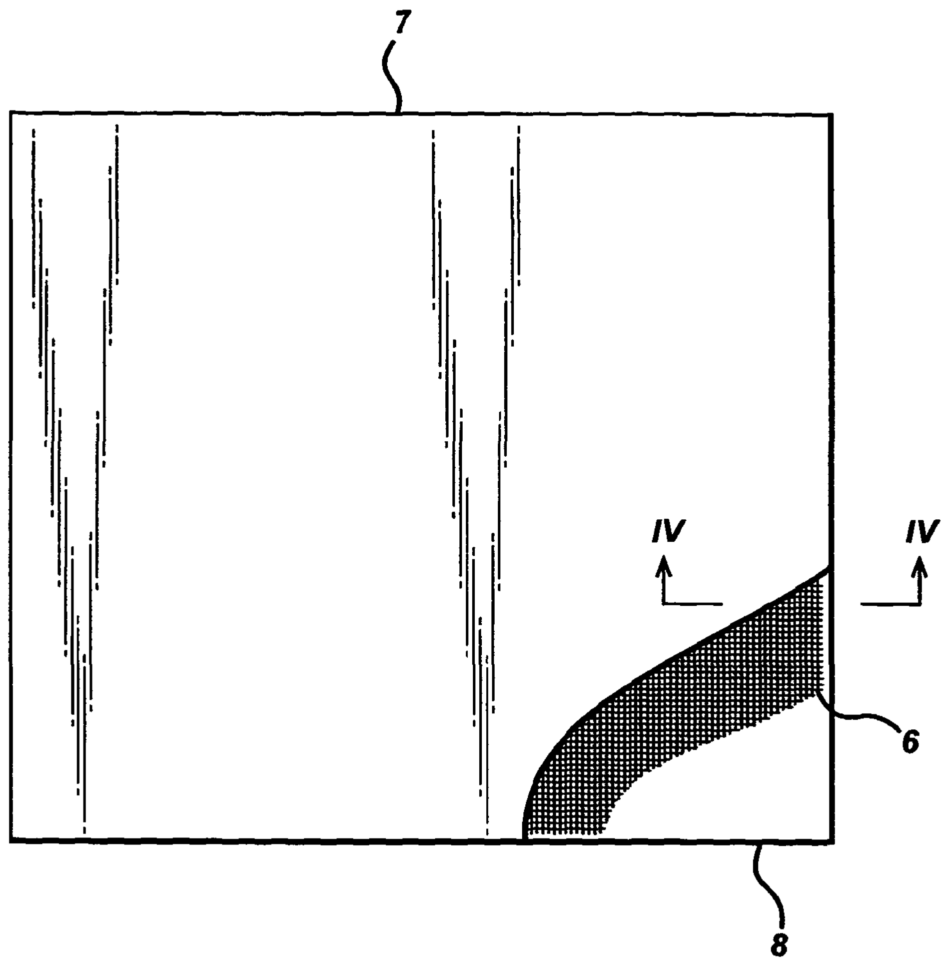


FIG. 4

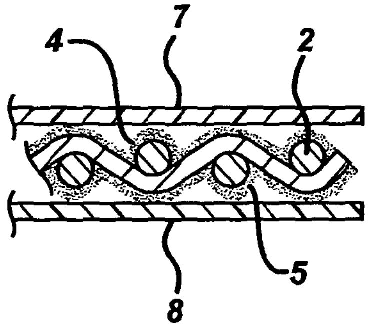


FIG. 5

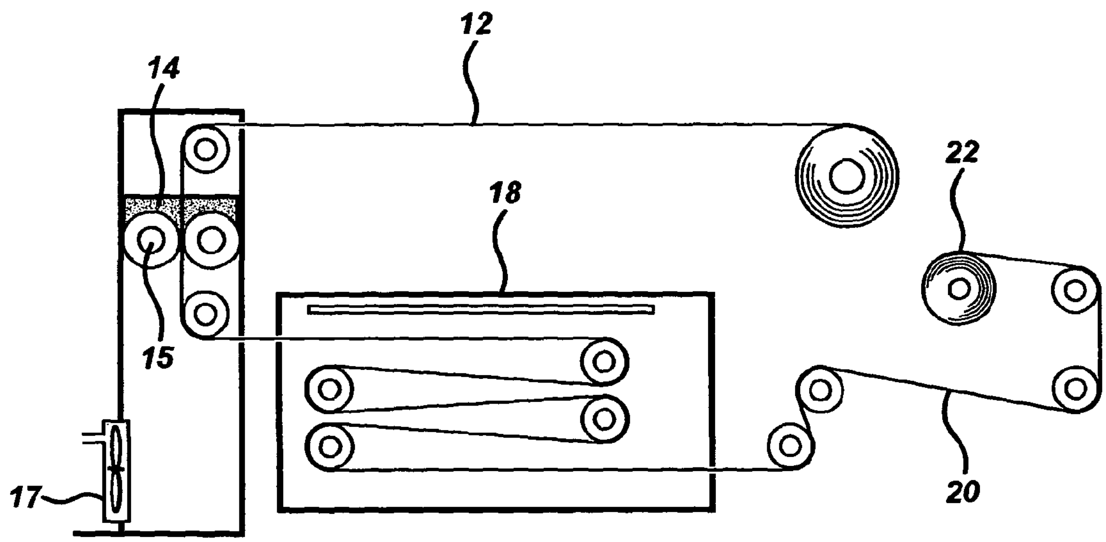


FIG. 6

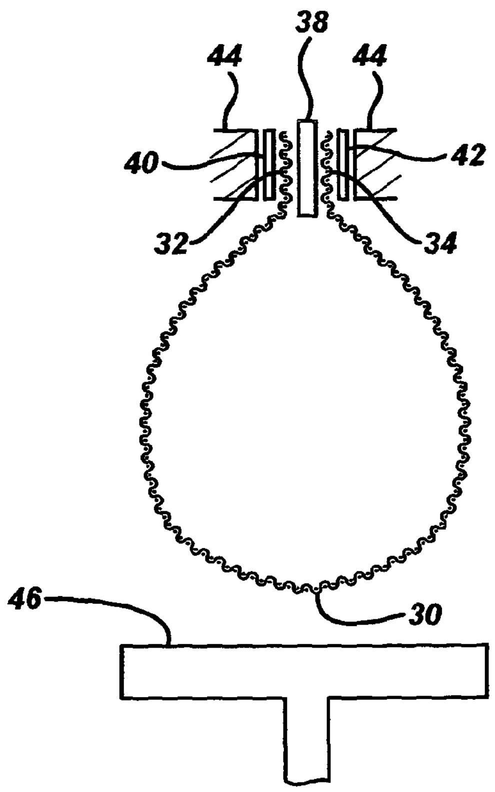
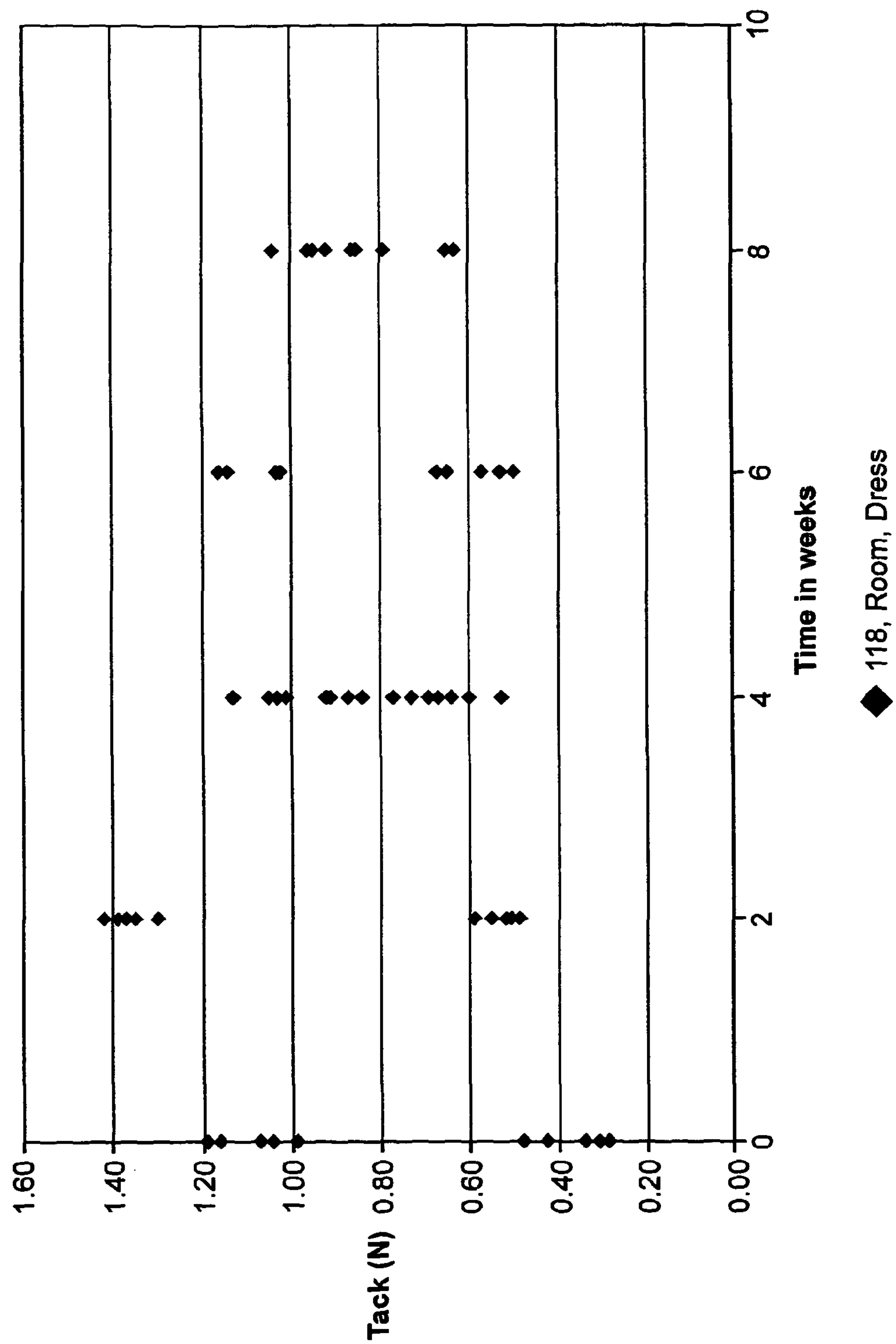


FIG. 7


Tack (N)
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
0
2
4
6
8
10
Time in weeks
118, Room, Dress

SILICONE GEL-COATED WOUND DRESSING

The present invention relates to wound dressings comprising a substrate coated on both surfaces with a tacky silicone gel, wherein the surfaces have different tackiness, and to methods of making such dressings.

Dressing materials for application to the surface of wounds should desirably be non-adherent to the moist wound surface, but sufficiently tacky to allow attachment of the dressing to intact skin around the wound and attachment to further dressing layers such as absorbent layers. For this purpose a soft or tacky hydrophobic material is suitable for the material. The wound contacting material should desirably be liquid-permeable to allow passage of wound fluid, especially for heavily exuding wounds such as burns. The material should also be non-irritating, inexpensive, and stable to common sterilization methods such as ionizing radiation.

Traditional "tulle gras" dressings generally consist of a layer of gauze coated with paraffin wax. Such dressings have a number of desirable properties, and for this reason have been used extensively for many years. Among these advantages are their high degree of conformability and deformability, and the fact that their tackiness makes them very easy to apply. That is to say, a tulle gras dressing applied to a wound will usually remain in place simply by adhesion of the paraffin wax to the patient's skin (or to itself in the case of a dressing wrapped around a finger, for example) while a securing bandage is applied. Tulle gras dressings are also quite inexpensive. However, tulle gras dressings do have a number of disadvantages. Principal amongst these is that, although initially non-adherent, they often become "dry" (in the sense of losing their paraffin coating) and consequently adhere to the wound to which they are applied. This effect is due to the paraffin coating becoming mobile at body temperatures and migrating into the wound or being absorbed into the backing of the dressing or bandage. In some cases, removal of a tulle gras dressing which has become dry in this way can cause considerable trauma. Indeed, it is quite common to have to soak tulle gras dressings in order to remove them. If tulle gras dressings are changed more frequently, in an attempt to avoid them becoming attached to the wound, this may delay wound healing and adds to nursing costs.

A further disadvantage of traditional tulle gras dressings is that fibres from the gauze may become incorporated in the wound, as may the paraffin coating of the dressing. Some authorities see the migration of paraffin into a wound as an undesirable effect and any paraffin found in a wound can be difficult to remove with normal aqueous wound cleansing agents. Moreover, the pores of the gauze may become occluded if the paraffin coating is too heavy or as a result of the mobility of the paraffin during use of the dressing. While occlusive dressings are appropriate in some circumstances, it is undesirable that the nursing staff should have no control over whether the dressing used is in fact occlusive.

Still further disadvantages of conventional tulle gras dressings are that they are effectively opaque and of somewhat unsightly appearance, and the paraffin can run during storage, making them particularly messy to apply.

EP-A-0251810 describes wound dressing materials that overcome the above disadvantages by replacing the paraffin wax coating of conventional tulle gras by a tacky or non-tacky, hydrophobic silicone coating on a gauze or mesh substrate. In certain embodiments, the gauze may be provided with a tacky silicone coating on one side and a non-tacky silicone coating having a different composition on the other side. Similar materials are described in WO-A-8705206.

EP-A-0342950 describes similar wound dressings having a non-adherent silicone coating. The adherence of the silicone is reduced by addition of an amine-extended polyurethane.

U.S. Pat. No. 6,846,508 describes medical adhesive devices having tacky silicone layers on both surfaces of a substrate. The material of the tacky layers may be the same or different, and the tackiness of the layers may be the same or different.

U.S. Pat. No. 5,891,076 describes scar dressings comprising a carrier material embedded in a layer of silicone gel which is tacky, and cover sheets over the silicone gel layers.

JP-A-10095072 describes a double-sided silicone adhesive tape for non-medical adhesive applications and having release sheets over the silicone adhesive.

The present invention provides a wound dressing product comprising: a substrate layer having an upper surface and a lower surface; a tacky silicone coating composition present on said upper surface and on said lower surface; and upper and lower release sheets covering said substrate and said tacky silicone coating composition on said upper and lower surfaces, respectively, and adhered to said surfaces by said tacky silicone coating composition, wherein said upper surface is less tacky than said lower surface whereby said upper release sheet can be removed from said upper surface more readily than said lower release sheet can be removed from said lower surface.

Suitably, the substrate is porous, whereby the substrate is permeable to the fluid. For example, the substrate may be a mesh or web or fabric suitably formed from a woven, nonwoven or knitted textile or a molded mesh.

In certain embodiments the substrate is a fabric such as a gauze, or a mesh, having an array of apertures. The size and shape of the apertures in the substrate are not critical, but the apertures should suitably be such as to ensure that the material can be adequately coated with silicone gel without them becoming occluded. The apertures generally have an aspect ratio of from 1:1 to 5:1, and preferably from 1:1 to 2:1. For example, the apertures may be approximately circular or approximately square. The apertures suitably have an average diameter of from 0.3 to 4 mm, and more suitably from 0.5 to 2 mm.

The substrate is suitably formed from any medically acceptable material, such as cellulose, polyolefins, polyesters, or polyamides. An especially suitable material is cellulose acetate gauze. Substrates having a weight of from 15 to 200 g/m^2 are generally found to be suitable for use in the products of the invention, and fabrics weighing from 50 to 150 g/m^2 are most suitable. For example, certain embodiments employ a fabric of from 80 to 120 g/m^2.

Suitably, the silicone-coated substrate product retains open apertures to allow passage of wound fluid through the coated substrate. For example, an array of apertures may extend through said silicone coatings and the substrate layer. The open area of the coated substrate in the final product may for example be from about 1% to about 70%, for example from about 10% to about 50%.

The dressing materials of the invention are characterized by tacky upper and lower silicone coatings on the substrate, wherein the upper and lower silicone coatings have different tackiness. This provides the advantage that both surfaces can be protected before use by cover sheets adhered to the coating by the tackiness thereof, but one of the cover sheets can be removed more easily than the other whereby application of the dressing is easier. Not only is it easier to selectively remove the first cover sheet if it is less strongly adhered than the second cover sheet, but also the resulting exposed less-adherent surface is more suitable for application to the wound surface. The second cover sheet can then be removed to expose a more adherent surface for application of secondary dressing layers, such as absorbent layers.

The difference in tackiness between the upper and lower silicone coatings is suitably selected to optimise the above properties. For example, the tackiness of the lower surface as measured by a loop tack test (described below) is suitably from 5% to 150% greater than the tackiness of the upper surface, more suitably from 20% to 100% greater, for example about 30% to 70% greater. Suitably, the tackiness of the surfaces as measured by the loop tack test is greater than about 0.3N. For example, they may be from about 0.4N to about 2N, more suitably from about 0.5N to about 1.5N. In embodiments, the tackiness of one surface is from about 0.4N to about 1N and the tackness of the other surface is from about 0.5N to about 1.5N.

Suitably, the above difference in tackiness can be achieved in materials wherein the silicone on said upper and lower surfaces is substantially chemically homogeneous. That is to say, wherein the same silicone prepolymer is coated onto the upper and lower surfaces, but differences in coating or curing conditions are used to achieve different tackiness in the upper and lower surfaces. Thus, both surfaces have been formed by curing the same fluid silicone prepolymer.

The term "chemically homogeneous" signifies that the chemical analysis (wt % silicon, carbon, oxygen, etc.) is the same on the upper and lower surfaces, but the tackiness may be different due to different degrees or type of cure between the surfaces and/or different coating thicknesses on the two surfaces. Thus, the silicone material forms a continuous chemically homogeneous phase having different tackiness on its opposing surfaces.

The total coating weight of the tacky silicone (combined upper and lower layers) is suitably from about 50 g/m^2 to about 500 g/m^2, for example from about 80 g/m^2 to about 200 g/m^2, typically from about 100 g/m^2 to about 150 g/m^2. The silicone is suitably a soft skin adhesive silicone composition. Suitably chemistry is described below. The silicone is suitably hydrophobic.

The effectiveness of encapsulation by silicone means that the substrate may be printed or dyed with decorative or informative matter with little danger of the ink or dye being released into the wound to which the dressing is applied. Visible indicia, such a colour or writing, may be provided on one or both of the surfaces of the substrate and/or on one or both cover sheets to indicate which sides of the product have the more/less tacky silicone coating and thus to indicate which cover sheet is removed first and which silicone surface is less tacky for application to the wound surface.

The cover sheets may comprise a film of polyethylene, polypropylene or fluorocarbons and papers coated with these materials. Suitably, the cover sheet is a release-coated paper sheet, such as a silicone release-coated paper sheet. Examples of silicone-coated release papers are POLYSLIK (Registered Trade Mark) supplied by H.P. Smith & Co., offered in various formulations to control the degree of adhesion of the paper to the adhesive surface.

In certain embodiments, one or both cover sheets may comprise two or more parts, such as a first removable part having a first edge and a second removable part that meets the first part along the first edge. Suitably, along each of said edges where the parts meet, one of the parts is folded back to provide a folded-back margin, and the other part overlaps the said folded-back margin. This provides an easy-to-grasp margin on each part in the region of overlap to assist removal of the cover sheet by the care giver.

In other embodiments, one or both cover sheets may comprise three parts, for example as described in detail in EP-A-0117632.

The products of the invention may be made into wound dressings for application to the surface of a wound by removing the top and bottom cover sheets. Suitably, the products of the invention consist essentially of the substrate, the silicone coatings, and the cover sheets. Suitably, the products of the invention are sterile and packaged in a microorganism-impermeable container.

In a further aspect, the invention provides a method of making a wound dressing material comprising:

- providing a substrate layer having an upper surface and a lower surface;
- coating said upper and lower surfaces of said substrate layer with a fluid silicone prepolymer composition; followed by
- thermally partially curing said silicone prepolymer composition to produce an intermediate material having a partially cured silicone composition on said upper and lower surfaces; followed by
- storing said intermediate material at a temperature below 50° C. for at least 2 days to allow equilibration of the silicone coatings on the upper and lower surfaces; followed by
- further curing said partially cured silicone composition by exposing said intermediate material to ionizing radiation, to produce a final material having tacky silicone coatings on said upper and lower surfaces.

In a further aspect, the invention provides a method of making a wound dressing material comprising:

- providing a substrate layer having an upper surface and a lower surface;
- coating said upper and lower surfaces of said substrate layer with a fluid silicone prepolymer composition; followed by
- thermally partially curing said silicone prepolymer composition to produce an intermediate material having a partially cured silicone composition on said upper and lower surfaces; followed by
- further curing said partially cured silicone composition by exposing said intermediate material to ionizing radiation, to produce a final material having tacky silicone coatings on said upper and lower surfaces,
- wherein either (a) said step of coating is applies unequal weights of the silicone coating composition to said upper and lower surfaces, and/or (b) said step of thermally partially curing applies different amounts of heat to said upper and lower surfaces, whereby said silicone coatings on said upper and lower surfaces have different tackiness following said further curing step.

The substrate layer is suitably as previously described for the products of the invention. Suitably, the substrate layer is permeable to the fluid silicone prepolymer composition. The step of coating may be performed in any conventional way, for example immersion, spraying, or doctor blade. The step of coating suitably comprises passing the coated substrate through nip rollers to ensure smooth coating and penetration of the coating composition. Suitably, the step of coating is followed by a step of blowing gas (such as air) through the substrate to ensure that the apertures in the material are open after coating.

The fluid silicone coating composition is suitably substantially or completely solvent-free. Suitably, both surfaces are coated with the same silicone coating composition. The methods of the present invention allow products having different tackiness on the upper and lower surfaces to be made with a single silicone coating composition on both surfaces.

Suitably, the silicone composition is a so-called soft skin adhesive silicone elastomer. Such silicones can be made by an addition reaction (hydrosilylation) between (a) a vinyl functional polydimethyl siloxane, such as bis-dimethyl vinyl PDMS, and (b) a hydrogen functional siloxane, such as dimethyl, methylhydrogen siloxane copolymers, hydrogen dimethylsiloxy terminated PDMS. The cure reaction is catalyzed by a hydrosilylation catalyst, such as a noble metal catalyst, suitably a platinum catalyst. Suitably the silicone prepolymer composition further comprises a polymerization inhibitor that is evaporated from said composition during said step of thermally partially curing, for example 2-methyl-3-butyn-2-ol. The polymerization inhibitor is suitably present in an amount of from about 0.001 wt. % to about 1 wt. %, for example from about 0.01 wt. % to about 0.1 wt. % before curing.

Silicone skin adhesive compositions are suitably supplied as two-part systems: Part A contains at least the vinyl prepolymer and the catalyst, while Part B contains the vinyl prepolymer and the SiH siloxane cross linker. The components are mixed immediately before use, optionally with addition of the polymerization inhibitor.

In embodiments, the silicone coating composition comprises or consists essentially of the following components:

(A) a diorganopolysiloxane having at least 2 alkenyl groups in each molecule;

(B) an organohydrogenpolysiloxane having at least 2 silicon-bonded hydrogen atoms in each molecule, in a quantity sufficient for the ratio between the number of moles of silicon-bonded hydrogen atoms in this component and the number of moles of alkenyl groups in component (A) to have a value of from about 0.6:1 to about 20:1,

(C) optionally a platinum group metal catalyst suitably in a quantity providing 0.1 to 500 weight parts as platinum group metal per 1,000,000 weight parts component (A); and

(D) a volatile polymerization inhibitor, suitably selected from: alkyne alcohols such as 2-methyl-3-butyn-2-ol, 3,5-dimethyl-1-hexyn-3-ol, and phenylbutynol; ene-yne compounds such as 3-methyl-3-penten-1-yne and 3,5-dimethyl-3-hexen-1-yne; tetramethyltetrahexenyl-cyclotetrasiloxane; and benzotriazole.

The diorganopolysiloxane, component (A), used in the instant invention is the base component of the total composition. This diorganopolysiloxane must contain at least 2 alkenyl groups in each molecule in order for this composition to cure into a rubbery elastic silicone rubber coating composition.

The diorganopolysiloxane (A) comprises essentially straight-chain organopolysiloxane with the average unit formula $R_nSiO_{(4-n)/2}$, wherein R is selected from substituted and unsubstituted monovalent hydrocarbon groups and n has a value of 1.9 to 2.1. R may be exemplified by alkyl groups such as methyl, ethyl, propyl, and others; alkenyl groups such as vinyl, allyl, and others; aryl groups such as phenyl, and others; and haloalkyl groups such as 3,3,3-trifluoropropyl and others. The diorganopolysiloxane (A) should have a viscosity at 25° C. of at least 100 centipoise (1 d Pa·s). When such factors as the strength of the silicone rubber coating membrane, and blendability are taken into account, the viscosity of diorganopolysiloxane (A) at 25° C. is preferably from 1,000 centipoise (1 Pa·s) to 100,000 centipoise (100 Pa·s). The diorganopolysiloxane (A) may be exemplified by dimethylvinylsiloxy-endblocked dimethylpolysiloxanes, dimethylvinylsiloxy-endblocked dimethylsiloxane-methylvinylsiloxane copolymers, and dimethylvinyl-siloxy-endblocked dimethylsiloxane-methylphenylsiloxane copolymers.

Component (B), an organopolysiloxane that contains at least 2 silicon-bonded hydrogen atoms in each molecule, is a crosslinker for the composition of the instant invention. The organopolysiloxane (B) may be exemplified by trimethylsiloxy-endblocked methyl-hydrogenpolysiloxanes, trimethylsiloxy-endblocked dimethylsiloxanemethylhydrogen-siloxane copolymers, dimethylphenylsiloxy-endblocked methylphenylsiloxanemethyl-hydrogensiloxane copolymers, cyclic methylhydrogenpolysiloxanes, and copolymers that contain the dimethylhydrogensiloxy unit and SiO4/2 unit. The organohydrogenpolysiloxane (B) should be added in a quantity that the ratio between the number of moles of silicon-bonded hydrogen atoms in this organohydrogenpolysiloxane and the number of moles of alkenyl groups in component (A) has a value of 0.6:1 to 20:1.

The platinum group metal catalyst, component (C), used in the compositions is a curing catalyst. The platinum group metal catalyst (C) may be exemplified by platinum micropowder, platinum black, chloroplatinic acid, platinum tetrachloride, olefin complexes of chloroplatinic acid, alcohol solutions of chloroplatinic acid, complexes between chloroplatinic acid and alkenylsiloxanes, rhodium compounds, and palladium compounds. The platinum group metal catalyst (C) should be added generally at 0.1 to 500 weight parts as platinum group metal per 1,000,000 weight parts component (A), and is preferably used at 1 to 50 weight parts as platinum group metal per 1,000,000 weight parts component (A). The reaction will not develop adequately at less than 0.1 weight parts, while additions in excess of 500 weight parts are uneconomical.

The coated substrate is then subjected to thermal curing to partially cure the silicone. The thermal coating is suitably performed continuously by passing the coated substrate through an oven. Suitable thermal curing conditions include exposure to a temperature of from about 80° C. to about 200° C., for example about 120° C. to about 180° C. for a time of from about 1 minute to about 10 minutes, for example about 1.5 minutes to about 5 minutes. The elevated temperature results in evaporation of the polymerization inhibitor from the silicone composition and therefore in polymerization of the silicone. The resulting material is chemically polymerized, but capable of further curing by ionizing radiation as explained further below.

The partially cured material has unequal tackiness of the silicone coating on the upper and lower surfaces. This unequal tackiness can be produced by (1) unequal coating weights of the silicone on the upper and lower surface, and/or (2) the step of blowing air through the coated substrate to open the apertures, which results in a higher coating weight of silicone on the surface that is downstream of the air flow, and/or (3) unequal amounts of heat supplied to the upper and lower surfaces in the oven resulting in different degrees of cure on the two surfaces.

The initial difference in tackiness of the upper and lower surfaces is typically rather greater than desired for the final product. However, the present inventors have found that the tackiness of the upper an lower surfaces gradually equilibrates if the partially cured material is stored at temperatures below about 50° C., for example ambient or near-ambient temperatures such as 10-50° C., for a period of from about 2 days to about 10 weeks. Therefore, suitably the partially cured material is stored at such temperatures for a period of at least about 2 days, suitably about 2 weeks to about 10 weeks, for example about 3 weeks to about 8 weeks before the final cure with ionizing radiation.

Suitably, the method of the invention further comprises applying upper and lower release sheets over said silicone composition on the upper and lower surfaces. Suitably, the upper and lower release sheets are applied intermediate said steps of thermally partially curing and storing, whereby, for example, the partially cured material having the cover sheets can be rolled up for the storage step.

The partially cured material is then subjected to a final cure with ionizing radiation. The ionizing radiation is suitably selected from e-beam radiation and gamma radiation. A variety of procedures for E-beam and gamma ray curing are well-known. The cure depends on the specific equipment used, and those skilled in the art can define a dose calibration model for the specific equipment, geometry, and line speed, as well as other well understood process parameters.

Commercially available electron beam generating equipment is readily available. For example, a Model CB-300 electron beam generating apparatus (available from Energy Sciences, Inc. (Wilmington, Mass.). Generally, a support film (e.g., polyester terephthalate support film) runs through a chamber. Generally, the chamber is flushed with an inert gas, e.g., nitrogen while the samples are e-beam cured. Multiple passes through the e-beam sterilizer may be needed.

Commercially available gamma irradiation equipment includes equipment often used for gamma irradiation sterilization of products for medical applications. Cobalt 60 sources are appropriate. Total absorbed doses are suitably from 20 to 60 kGy, more suitably from about 35 to 50 kGy and dose rates are suitably about 7 to 8 kGy/hour.

Suitably, the method further comprises the step of packaging the intermediate material in a microorganism-impermeable container prior to said step of further curing, and wherein said step of further curing also sterilizes the material.

The methods of the invention may be used to make any products according to the invention. Any feature disclosed herein in relation to any one or more aspects of the invention is suitable for use in any of the other aspects defined herein.

Specific embodiments of the invention will now be described further, by way of example, with reference to the accompanying drawings, in which:

FIG. **1** shows a perspective view of a product according to the invention packaged in a microorganism-impermeable pouch;

FIG. **2** shows a perspective exploded view of a product according to the invention;

FIG. **3** shows a top plan view partially cut away of the product of FIG. **2**;

FIG. **4** shows an enlarged partial cross-section through the product of FIG. **2**;

FIG. **5** shows a schematic view of an apparatus for making a product according to the method of the invention;

FIG. **6** shows a schematic diagram of the apparatus used for the loop tack measurement test; and

FIG. **7** shows a graph of measured loop tack adhesion for upper and lower surfaces of materials made in accordance with the present invention, wherein the samples have been stored for different times prior to the irradiation curing step.

Referring to FIGS. **1** to **4**, the product **1** according to the invention comprises a substrate **2** of cellulose acetate gauze of density 107 grams per square meter nominal, having upper and lower surfaces **4**,**5** coated with a hydrophobic, tacky, crosslinked silicone gel. The silicone composition penetrates the gauze substrate to form a single, chemically homogeneous silicone phase on the upper and lower surfaces. The coated substrate **6** has an array of apertures extending through the substrate and the silicone to allow passage of wound fluid through the material. The tackiness of the coated upper surface **4** is approximately 50% greater than the tackiness of the coated lower surface **5**, as determined by the loop tack test described below. The nominal total coating weight of the silicone is 120-130 grams per square meter.

Identical release-coated cover sheets **7**,**8** are applied to the upper and lower silicone-coated surfaces **4**,**5**. In use, the lower release sheet **8** is removed first to expose the less tacky lower surface **5** of the dressing material. It is relatively easy to selectively remove the lower release sheet **8** because of the lower adherency of this sheet to the material compared to the upper release sheet **7**. The lower and/or upper release sheets may further comprise indicia to identify the release sheet to be removed first. The lower surface **5** may then be applied to a wound surface, followed by removal of the upper release sheet **7** and application of secondary dressing elements such as an absorbent layer.

Referring to FIG. **1**, the product **1** is shown sterile and packaged in a microorganism-impermeable envelope **3** having a transparent window **10**.

Referring to FIG. **5**, the process according to the invention starts from a continuous web of cellulose acetate gauze **12** that is passed through a fluid silicone coating composition **14** and nip rollers **15** to coat and impregnate the gauze with the silicone composition. The silicone coating composition is prepared by mixing Components A and B of a soft silicone skin adhesive silicone elastomer kit supplied by Dow Corning under product reference Q7-9177. The components are mixed in weight ratio 50:50. Component A comprises a bis-dimethylvinyl terminated polydimethylsiloxane and a platinum catalyst. Component B comprises a bis-hydride terminated polydimethylsiloxane. To the mixture is added 2-methyl-3-butyn-2-ol inhibitor at a concentration of 0.02 wt. %.

The coated substrate then passes over a blower **17** to open the apertures of the coated substrate that may have been occluded by the silicone.

The coated gauze is then passed through an oven **18** held at 150° C. Typical conditions are 5 passes at 4.2 m/min, total residence time 1.5 minutes. This results in thermal partial cure of the silicone coating. The coated material is then allowed to cool, and release coated paper cover sheets (not shown) are then continuously applied to the upper and lower surfaces at location **20** and the material is rolled up on roll **22** for equilibration.

The rolls **22** of thermally cured and interleaved material are allowed to equilibrate at controlled temperature (20-25° C.) for 4-6 weeks. The material is then cut and packaged as shown in FIG. **1**, followed by gamma irradiation with 35-50 kGy of Cobalt 60 radiation at 7-9 kGy/hr to sterilize the products and complete the cure. The irradiation curing results in a further increase in both hardness and tackiness of the silicone coating.

Procedure 1: Measurement of Surface Tackiness by the Loop Tack Test

The tackiness of the silicone coatings produced by the methods of the invention was measured in a tensile tester, such as an Instron tester, using the set-up shown in FIG. **6**.

Samples of the coated fully cured gauze having the release cover sheets attached were cut to dimensions 5×9.5 cm. Margins of 1 cm were marked out along the long edges by drawing straight lines 1 cm from the long edges. The cover sheets were removed, and the sheet of coated gauze **30** was looped around and the 1 cm margins **32**,**34** on opposed edges of one surface (opposite the surface being measured) were applied firmly to opposite sides of a 2 mm thick metal spacer bar **38**. Strips of polypropylene film 1 cm wide **40**,**42** were then applied to the opposite surfaces of the coated gauze opposite the spacer bar **38** to prevent the coated gauze from adhering to the jaws of the measurement device.

The assembly of polypropylene strips, coated gauze and spacer bar was then gripped in the jaws **44** of the Instron tester. The loop of coated gauze **30** having the surface under test outermost was then lowered onto a clean polycarbonate surface **46** of dimensions 15.5 cm×3.8 cm so that the loop adheres to the surface, and raised to detach the loop from the surface. Lowering and raising are performed at 300 mm/min, and the minimum distance between the jaws **44** and the polycarbonate surface **46** is 15 mm. The measured tack (in Newtons) is the maximum force measured while detaching the loop from the surface. Average of three measurements was used.

FIG. **7** shows tack data obtained by the above for samples of the coated gauze obtained in accordance with the invention. The coating weight was 118 grams per square meter. Measurements were made on samples sterilized after storage at 25° C. and 4% relative humidity for 0, 2, 4, 6, and 8 weeks. The upper and lower surfaces initially have very different tack as evidenced by the two groups of measurements at around 0.4N and 1.1N, but the tack converges on storage after about 4 weeks such that the final tack of the upper surface is about 1.0N and the final tack of the lower surface is about 0.7N.

The above examples have been described by way of illustration only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

The invention claimed is:

1. A method of making a wound dressing material comprising:

providing a substrate layer having an upper surface and a lower surface;

coating said upper and lower surfaces of said substrate layer with a fluid silicone prepolymer composition; followed by

thermally partially curing said silicone prepolymer composition to produce an intermediate material having a partially cured silicone composition on said upper and lower surfaces; followed by

further curing said partially cured silicone composition by exposing said intermediate material to ionizing radiation, to produce a final material having tacky silicone coatings on said upper and lower surfaces,

wherein said step of coating applies unequal weights of the fluid silicone prepolymer composition to said upper and lower surfaces, whereby said silicone coatings on said upper and lower surfaces have different tackiness following said further curing step.

2. A method according to claim **1**, further comprising storing said intermediate material at a temperature below 50° C. for at least 2 days to allow equilibration of the silicone coatings on the upper and lower surfaces.

3. A method according to claim **2**, wherein said step of storing is carried out for a time of from 2 weeks to 10 weeks.

4. A method according to claim **1**, wherein said fluid silicone prepolymer composition comprises: a vinyl functional polydimethylsiloxane, a hydrogen functional siloxane, a hydrosilylation catalyst, and a polymerization inhibitor that is evaporated from said composition during said step of thermally partially curing.

5. A method according to claim **1**, further comprising applying upper and lower release sheets over said silicone composition on the upper and lower surfaces.

6. A method according to claim **5**, wherein said upper and lower release sheets are applied intermediate said steps of thermally partially curing said silicone prepolymer composition and further curing said partially cured silicone composition.

7. A method according to claim **1**, further comprising the step of packaging the intermediate material in a microorganism-impermeable container prior to said step of further curing, and wherein said step of further curing also sterilizes said material.

8. A method according to claim **1**, wherein said step of thermally partially curing applies different amounts of heat to said upper and lower surfaces.

9. A method of making a wound dressing material comprising:

providing a substrate layer having an upper surface and a lower surface;

coating said upper and lower surfaces of said substrate layer with a fluid silicone prepolymer composition; followed by

thermally partially curing said silicone prepolymer composition to produce an intermediate material having a partially cured silicone composition on said upper and lower surfaces; followed by

further curing said partially cured silicone composition by exposing said intermediate material to ionizing radiation, to produce a final material having tacky silicone coatings on said upper and lower surfaces,

wherein said step of thermally partially curing applies different amounts of heat to said upper and lower surfaces, whereby said silicone coatings on said upper and lower surfaces have different tackiness following said further curing step.

10. A method according to claim **9**, wherein said step of coating applies unequal weights of the fluid silicone prepolymer composition to said upper and lower surfaces.

11. A method according to claim **9**, further comprising storing said intermediate material at a temperature below 50° C. for at least 2 days to allow equilibration of the silicone coatings on the upper and lower surfaces.

12. A method according to claim **11**, wherein said step of storing is carried out for a time of from 2 weeks to 10 weeks.

13. A method according to claim **9**, wherein said fluid silicone prepolymer composition comprises: a vinyl functional polydimethylsiloxane, a hydrogen functional siloxane, a hydrosilylation catalyst, and a polymerization inhibitor that is evaporated from said composition during said step of thermally partially curing.

14. A method according to claim **9**, further comprising applying upper and lower release sheets over said silicone composition on the upper and lower surfaces.

15. A method according to claim **14**, wherein said upper and lower release sheets are applied intermediate said steps of thermally partially curing said silicone prepolymer composition and further curing said partially cured silicone composition.

16. A method according to claim **9**, further comprising the step of packaging the intermediate material in a microorganism-impermeable container prior to said step of further curing, and wherein said step of further curing also sterilizes said material.

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